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Supreme Court of the United States

AETNA HEALTH, INC.
Petitioner,

v.

JUAN DAVILA
Respondent.

CIGNA HEALTHCARE OF TEXAS, INC., AND
CIGNA CORPORATION
Petitioner,

v.

RUBY R. CALAD, *et al.*
Respondent.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR AAHP-HIAA, THE BLUE CROSS BLUE SHIELD ASSOCIATION, AND THE AMERICAN BENEFITS COUNCIL AS AMICI CURIAE SUPPORTING PETITIONERS

STEPHANIE W. KANWIT
CHRISTINA S. YEHLE
AAHP-HIAA
1129 20th Street, N.W.
Washington, D.C. 20036
(202) 778-3202

SETH P. WAXMAN
Counsel of Record
EDWARD C. DUMONT
KENNETH A. BAMBERGER
WILMER, CUTLER & PICKERING
2445 M Street, N.W.
Washington, D.C. 20037
(202) 663-6000

Counsel for Amicus Curiae AAHP-HIAA

ADDITIONAL COUNSEL LISTED ON INSIDE COVER

ALAN JAY LIPSITZ
BLUECROSS BLUESHIELD
ASSOCIATION
1310 G Street, N.W.
Washington, D.C. 20005
(202) 942-1278

Counsel for BlueCross BlueShield Association

SUSAN RELLAND
LYNN DUDLEY
AMERICAN BENEFITS COUNCIL
1212 New York Ave., N.W.
Washington, D.C. 20005
(202) 289-6700

Counsel for American Benefits Council

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The American Association Of Health Plans-Health Insurance Association Of America, Inc., The BlueCross BlueShield Association, and The American Benefits Council respectfully submit this brief as amici curiae supporting petitioners.[1]

[1] This brief was prepared in its entirety by amici and their counsel. No monetary contribution toward the preparation or submission of this brief was made by any person other than amici, their members, and their counsel. Petitioners and respondents have consented to the filing of this brief in letters filed with the Clerk.

INTERESTS OF AMICI

The American Association Of Health Plans-Health Insurance Association Of America, Inc. (AAHP-HIAA) is the national association representing the private health plan and insurer community. AAHP-HIAA's mission is to advance health care quality and affordability through leadership in the health care community, advocacy, and the provision of services to its members. AAHP-HIAA represents nearly 1,300 member companies that administer or insure benefits, including health, pharmaceutical, long-term care, disability, and supplemental coverage, to more than 200 million Americans, the majority of whom are participants in or beneficiaries of employee benefit plans under the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*

The BlueCross BlueShield Association comprises 41 independent, locally operated BlueCross and BlueShield Plans. The BlueCross and BlueShield companies provide, through relationships with employers, employee benefits plans, and direct contracts with subscribers, health insurance to private and public employees and individuals, including fee-for-service programs, health maintenance organizations, preferred provider organizations, and a variety of other offerings. They also provide third-party administrative services to private and public employee benefits plans. Collectively, the BlueCross and BlueShield companies furnish health care coverage to 88.6 million—or one in four—Americans, making them (as a group) the largest U.S. entity offering health insurance and benefits.

The American Benefits Council is a broad-based, nonprofit trade association founded in 1967 to protect and foster the growth of this nation's privately sponsored employee benefit plans. The Council's members include both small and large employer-sponsors of employee benefit plans, including many Fortune 500 companies. Its members also include employee benefit plan support organizations, such as actuarial and consulting firms, insurers, banks, investment firms, and other professional benefit organizations. Collectively,

its more than 250 members sponsor and administer plans covering more than 100 million plan participants and beneficiaries.

SUMMARY OF ARGUMENT

Since 1974, ERISA's establishment of a uniform system for regulating employee benefit plans has fostered the development of widespread, voluntary, employment-based health care coverage. Under that system, employers and unions have taken up the challenge of sponsoring health benefit plans to provide employees and other beneficiaries with substantial financial protection from the high cost of health care. This private benefits system, in which specific terms of coverage are chosen by particular sponsors, as appropriate for their resources and the needs of a given group, has allowed the development of a wide variety of specific benefit plans. Voluntary, employment-based plans now provide coverage for many health care costs for over 130 million individuals in the United States.

All such plans ultimately reflect the sponsors' and participants' shared interest in obtaining the best possible coverage that can be provided at a sustainable cost. The cost portion of this equation presents particular challenges, because of the special features of the health-care marketplace. Responding to economic challenges such as steep increases in the cost of hospital care and prescription drugs, both public and private health benefit administrators have developed an array of techniques for ensuring the cost-effectiveness of the benefits they provide. These techniques, generally grouped under the term "managed care," are not concerned with what care a beneficiary may or may not choose and be able to procure with individual resources. They address instead what measures the party that is administering the group plan will recognize (and, indeed, sometimes encourage) as cost-justified. Such determinations go to the heart of the administrator's obligation to manage limited funds prudently on behalf of *all* the beneficiaries who will need to draw on its resources, in accordance with the contractually specified terms of the plan.

It is important to recognize that evidence-based coverage guidelines and similar benefit-management techniques may promote, as well as restrain, the use of benefits to pay for care that is medically appropriate—and the need for which might or might not be recognized or pursued under traditional, fee-for-service coverage. This reflects the fact that the interests of plan sponsors, beneficiaries, and administrators are all well served when evidence-based techniques ensure that a plan's resources are used to pay justified amounts for care that is likely to be genuinely beneficial. To that end, as well, plans provide internal mechanisms for establishing exceptions to general guidelines, and for the rapid review of initial coverage-management decisions. There are also options for external review, including appeal to the courts under ERISA. Finally, in important respects the sort of decisions made under coverage-management provisions do not differ in kind from the "medical necessity" determinations that have always been required for insurance coverage under any sort of plan: They are simply more structured, and better timed. Pre-utilization review of coverage protects both beneficiaries and health-care providers from incurring expenses based on an unjustified expectation that a third-party payor will agree that those expenses fall within its reimbursement obligations.

For these reasons, one would not expect coverage-management techniques of the sort at issue in these cases to adversely affect the quality of care provided to plan beneficiaries, as compared to traditional indemnity insurance plans. Indeed, empirical studies confirm that although managed-care organizations (MCOs) administer medical benefits at significantly lower cost than more traditional insurance, beneficiaries covered by MCOs receive care of the same or even higher quality.

Although it has succeeded in providing high-quality health coverage for millions of Americans, the employment-based coverage system fostered by ERISA is under severe strain from rapidly increasing health care costs—in particular, the sorts of prescription drug and hospitalization costs

that are implicated in these cases. Particularly in light of these pressures, the Fifth Circuit was wrong to adopt an interpretation of federal law that would permit state tort suits based on plans' coverage decisions. There is no reason to believe that such suits are necessary to protect plan beneficiaries, or in particular to supplement the carefully selected, nationally uniform remedies already provided by Congress in ERISA. To the contrary, allowing state suits would be affirmatively harmful. By increasing complexity, reducing predictability, and otherwise increasing costs, such suits would undermine precisely the uniformity and efficiency that Congress sought to foster in ERISA. The response of plan sponsors is not hard to predict: Some will restrict benefits, including replacing discretionary decisions with categorical exclusions, or further increase direct employee costs. Others may simply discontinue, or decline to institute, health benefits. Either way, allowing state suits would significantly undermine Congress's goal of encouraging employment-based health coverage, without promising any counter-balancing increase in protection for those individuals who remain covered by ERISA plans.

ARGUMENT

I. VOLUNTARY EMPLOYEE HEALTH BENEFIT PLANS, SPONSORED BY EMPLOYERS AND SUBJECT TO UNIFORM FEDERAL REGULATION UNDER ERISA, ARE THE FOUNDATION OF THE NATION'S HEALTH COVERAGE SYSTEM

One significant challenge for contemporary societies is providing widespread access to high-quality health care, at a sustainable cost. In the United States this goal has been pursued largely—and very successfully—through the mechanism of voluntary health benefit plans that are sponsored by employers (including federal and state governments) or unions, and provide coverage to groups of employees.

This system takes advantage of private interests and mechanisms to produce a system that is both robust and flexible. Plan sponsors have a strong interest in providing

employees with high-quality health coverage, both as a form of compensation and because such coverage leads to higher productivity. Employees have a strong interest in obtaining coverage, and in benefiting from the efficiencies made possible by group plans. Sponsors and employees together bear the cost of coverage, and thus have a mutual interest in the availability of plans that provide the mixture of comprehensiveness and affordability that is most appropriate for their particular circumstances. Finally, health insurers and benefit administrators have strong incentives to satisfy these demands by providing sponsors and employees with a wide variety of potential plans, all of which will seek to provide covered individuals with the most attractive possible combinations of coverage and price.

For 30 years, ERISA has encouraged and protected the development of this privately-ordered approach to health care coverage. "Nothing in ERISA requires employers to establish employee benefits plans. Nor does ERISA mandate what kind of benefits employers must provide if they choose to have such a plan." *Lockheed Corp.* v. *Spink*, 517 U.S. 882, 887 (1996). Rather, the Act enables and facilitates the voluntary establishment of plans, on whatever terms are chosen by particular sponsors and groups of employees.

One principal way it does this is by protecting plan sponsors, which frequently have employees and operations in many States, from the burdens of having to comply with multiple regulatory regimes. In framing ERISA, Congress recognized that while some regulation was necessary, the overall costs of compliance would inevitably affect whether plans would be established, and what level of actual benefits they could provide. Because inefficiency in regulation would ultimately hurt actual or prospective plan participants, Congress concluded that "employee benefit plans would prosper best if regulated by the federal government without

state involvement."[2] Accordingly, "[o]ne of the principal goals of ERISA is to enable employers to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits." *Egelhoff* v. *Egelhoff*, 532 U.S. 141, 148 (2001) (internal quotation marks and citation omitted). "Uniformity is impossible, however, if plans are subject to different legal obligations in different States." *Id.* The exclusive remedy provisions at issue in these cases, which protect plan administrators against state-law challenges to their individual coverage determinations outside the carefully balanced remedial framework provided by ERISA itself, are of central importance in maintaining the efficiency and predictability that the Act was intended to ensure.[3]

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[2] William J. Kilberg & Paul D. Inman, *Preemption of State Laws Relating to Employee Benefit Plans: An Analysis of ERISA Section 514*, 62 Tex. L. Rev. 1313, 1313-14 (1984); *see* H.R. Rep. No. 93-533, at 12 (1974), *reprinted in* 1974 U.S.C.C.A.N. 4639, 4650 ("The uniformity of decision which the act is designed to foster will help administrators, fiduciaries and participants to predict the legality of the proposed actions without the necessity of reference to varying state laws.").

As this Court has recognized:

> An employer that makes a commitment systematically to pay certain benefits undertakes a host of obligations, such as determining the eligibility of claimants . . . [and] making disbursements . . . . The most efficient way to meet these responsibilities is to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits. Such a system is difficult to achieve, however, if a benefit plan is subject to differing regulatory requirements in differing States. [If that were the case a] plan would be required to . . . process claims in a certain way in some States but not in others . . . .

Fort Halifax Packing Co. v. *Coyne*, 482 U.S. 1, 9 (1987).

[3] Sponsors of ERISA benefit plans may fund benefits directly, or provide them by purchasing insurance. Self-funded plans are regulated entirely by federal law, *see, e.g.*, 29 U.S.C. § 1135 (giving Secretary of Labor general authority to prescribe regulations under ERISA), while insurance purchased by a plan remains subject to state regulation in important respects, *see generally UNUM Life Ins. Co.* v. *Ward*, 526 U.S. 358,

Under the federal oversight provided by ERISA, the voluntary approach to employee health coverage has been a remarkable success. Employer and union sponsors, in conjunction with employees themselves, have committed huge resources to health benefit plans. Employment-based health plans are the most common type of health coverage in the United States, and ERISA-covered group health plans cover more than 130 million Americans.[4] Indeed, such plans are the cornerstone of the country's health care financing system.

II. COST-EFFECTIVENESS MEASURES ARE ESSENTIAL TO PROMOTE BOTH QUALITY AND COST-EFFICIENCY IN A VOLUNTARY EMPLOYMENT-BASED HEALTH BENEFITS SYSTEM

The success of the voluntary employment-based health benefits system is due not only to the relatively uniform regulatory regime established by ERISA, but also to the way that plan administrators and health insurers have been able to modify and adapt the traditional fee-for-service model of health insurance to address the special challenges posed by modern American health care economics. As a legal matter, the adaptations of "managed care," such as the step-therapy drug formulary and the hospital utilization review requirement at issue in these cases, do not differ fundamentally from the sort of "medical necessity" or "reason-

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367 n. 2 (1999). In either event, the *remedies* available for allegedly improper denials of coverage by a plan administrator in individual cases are defined carefully, and exclusively, by federal law. ERISA § 502(a)(1)(B) authorizes participants and beneficiaries to bring a civil action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." 29 U.S.C. § 1132(a)(1)(B). ERISA's civil enforcement remedies constitute the "exclusive vehicle for actions by ERISA-plan participants and beneficiaries asserting improper processing of a claim for benefits." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 52 (1987).

[4] *See* Employee Benefit Research Institute, *Special Report and Issue Brief, EBRI Research Highlights: Health Benefits* 5 (May 2003).

able and necessary costs" limitations that have always been a feature of the coverage provided by traditional indemnity insurance. They have, however, evolved dynamically in ways that allow intelligent management of scarce plan coverage dollars, while preserving, or even enhancing, the availability and application of financial resources to pay for high-quality, truly effective patient care.

A. Health Care Economics Pose Acute Challenges To Providing Broad, Affordable Coverage

Health care is a good for which demand is both acute and, in practical terms, inexhaustible. Moreover, notions of what is encompassed within standard "health care" coverage (as opposed to, for example, cosmetic or otherwise elective procedures) are prone to rapid expansion in a modern and relatively wealthy consumer economy. Given these robust and expanding demands, the American healthcare industry is continually generating new treatments, techniques, devices, and drugs that offer (or seem to offer) consumers of health care tremendous potential benefits—at, quite often, tremendous potential cost.

The trouble with this market dynamic lies in the way that individual health care "consumption" decisions typically get made. At a moment of need an insured patient, while the ultimate "consumer" of the care, typically lacks both the expertise to make informed decisions for himself, and any material sensitivity to price. The treating physician is guided by professional judgment and her pattern of practice, but may, as a practical matter, lack complete or fully up-to-date information about the risks and benefits (or relative costs) of all available options.[5] The physician is also likely subject to

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[5] A comprehensive national study of health care quality by researchers from the RAND Foundation found a substantial gap, for a wide range of illnesses, between what practicing physicians recommend to their patients and what medical scientists would describe as appropriate treatment. Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered*

her own set of time constraints, patient-relations concerns, and financial incentives.[6] Meanwhile, a health insurer or benefit plan administrator may have the ability to centralize and take account of large amounts of relevant information on cost as well as efficacy of a particular treatment or procedure. Under the traditional fee-for-service insurance model, however, an insurer or administrator lacks effective mechanisms for factoring that information into the decision whether the plan will pay for particular proposed treatments—at least, before the costs have already been incurred.

B. Cost-Effectiveness Measures Permit Plan Sponsors To Offer The Broadest Access To High-Quality Health Benefits At The Lowest Cost

These conditions make it difficult for conventional market forces to generate health care consumption choices that make economic sense from the point of view of an employee benefit plan (and its group of beneficiaries) as a whole. Of course, a plan administrator making individual coverage decisions, or an insurer that has contracted to provide specified benefits at an agreed price, is not interested in precluding an individual beneficiary from pursuing any particular course of treatment, whatever its cost or likely effectiveness, with the beneficiary's own resources. Such an administrator or insurer is, however, centrally concerned with determining

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to Adults in the United States, 348 New Eng. J. Med. 2635 (2003). Practioners failed to provide appropriate care about 46% of the time, while about 11% of the time they provided care that was not indicated or was even potentially harmful. *Id.* at 1641. The lead author concluded that "[w]e need to fundamentally re-engineer the way that health care is delivered" by relying on information technology systems, rather than individual practitioners, as the key to higher quality care. Editorial, *The Deeper Problem*, Wash. Post, June 29, 2003, at B6 (quoting Dr. McGlynn).

[6] *See Pegram* v. *Herdrich*, 530 U.S. 211, 218 (2000) ("In a fee-for-service system, a physician's financial incentive is to provide more care, not less, so long as payment is forthcoming.").

what specific costs the *plan* has or has not promised to bear. That question goes to the heart of the administrator's or insurer's obligation to manage the plan's funds prudently, on behalf of *all* the beneficiaries who are entitled, and will need, to draw on its limited resources.[7]

These concerns are critical to the ERISA model of voluntary employment-based coverage. The resources available to a plan are determined by what the sponsor and covered employees are willing to contribute. For that level of resources, the highly competitive market for group insurance or plan administration services will offer a variety of plans, adapted to the different situations or preferences of a given sponsor and employee group. The common theme of both demand and offerings, however, will be to achieve the most effective, highest quality coverage possible for the entire group, at the lowest possible cost.

In pursuing that goal, insurers and health plans—along with, and sometimes led by, public-sector care-delivery systems, such as Medicare and the Veterans Administration health system—have developed the array of cost- and quality-management techniques that are generally grouped under the heading "managed care." Like a traditional indemnity insurer, a managed-care organization (MCO) typically determines whether it will pay for particular services, prescription drugs, or other care based on whether the care received or desired was or is medically necessary and appropriately priced under given circumstances. The MCO, however, will typically use active techniques to promote the efficient use of plan funds. These may include, for example, the

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[7] A plan sponsor is free to design its plan to provide any type and level of benefits it chooses. That choice does not implicate any fiduciary duty. *See, e.g., Pegram*, 530 U.S. at 226-27. Once the terms of the plan have been set, determinations concerning whether an individual situation is or is not covered by those terms may have a medical aspect, but in the end they are acts of plan administration that reflect, and affect, the economics of the entire plan. They involve what care a plan has promised to pay for, not what care a doctor may recommend, or the patient may choose to receive.

sort of utilization-review procedures involved in these cases. In *Davila*, Aetna employed a standardized, evidence-based "step therapy" guideline in determining that it would not pay for an expensive new prescription drug in the absence of some documented reason not to use a clinically similar and less expensive medication. Likewise, in *Calad*, Cigna refused to promise payment for a hospital stay that exceeded the standard period its guidelines recognized as reasonable for a particular procedure, in the absence of specifc evidence that Calad's circumstances justified a longer stay. These sorts of determinations concerning what a given plan will and will not pay for, absent evidence about a particular beneficiary's specific circumstances, are core features of contemporary health-benefit management.[8]

For present purposes, there are at least three important points to be made about such benefit-management techniques. *First*, these and similar evidence-based coverage guidelines can promote, as well as constrain, use of benefits. Plans almost uniformly have, for example, established programs to promote the use of treatments that have been proven effective (such as prescribing beta blockers for heart-attack patients); to encourage preventive care, such as immunizations and diagnostic screening tests for cancer; and to promote proactive treatment-management for patients with chronic conditions such as asthma, diabetes, and heart disease.[9] The point is that insurers and plan administrators,

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[8] Voluntary plans have almost universally adopted managed care techniques. In 1988, 16% of covered workers were enrolled in HMOs, whereas 73% were still enrolled in traditional indemnity insurance plans. Kaiser Family Foundation & Health Research and Educational Trust, *Employer Health Benefits 2003 Annual Survey* 71 Ex. 5.1 (2003) ("Kaiser Foundation 2003 Survey"), *available at* http://www.kff.org/insurance/employer.cfm. By 1996, 27% of employees were enrolled in traditional indemnity plans, while 73% were enrolled in some form of MCO plan. This year, 95% of covered employees are enrolled in some type of MCO plan. *Id.*

[9] *See* AAHP, *Highlights of 2002 AAHP Annual Survey of Health Plans* (2003).

who compete for the business of plan sponsors and their employees, have no incentive to design systems that deny coverage for no good reason—particularly when, as is typically alleged by plaintiffs, the denial of some relatively inexpensive item or service would likely lead to a bad medical outcome that would then require additional, much more expensive, care. Rather, the interests of plan sponsors, beneficiaries, and plan administrators are all well served when evidence-based techniques are brought to bear to help ensure that the plan's resources are being used to pay as much as is necessary for care that is likely to work—but nothing extra for care that is not likely to improve either safety or outcomes.

Second, an initial decision to pre-approve payment for a particular procedure or drug is subject to rapid appeal and review within the plan structure, and then often by independent outside reviewers.[10] This sort of review is neither uncommon nor unrealistic: some 250,000 initial coverage denials are appealed annually, and many of the appeals are successful.[11] So far as appears, however, the respondents in these cases made no effort to pursue such an appeal.

Third, in important respects, the sort of coverage decisions that are made under plan pre-approval provisions are not different in kind from the "medical necessity" determinations that have always been required for coverage under any health insurance plan. The principal difference between the two is not the nature of the decision, but its structure and timing. Under a managed-care arrangement, it is clear what sorts of care require special authorization for coverage, and exactly what supporting evidence will be required. A beneficiary whose request for coverage is denied is, of course, free to seek the care at issue in any

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[10] *See infra*, pp. 23-24.

[11] *See* C. Roan Gresenz et al., *Patients in Conflict With Managed Care: A Profile of Appeals in Two HMOs*, Health Affairs, July/Aug. 2002, at 189, 191.

event, and a doctor, hospital, or pharmacy is free to provide it—just as would be true under a traditional, fee-for-service plan. The pre-approval process, however, protects both beneficiaries and providers from incurring expenses based on an unjustified expectation that a third-party payor will agree that those expenses fall within its reimbursement obligations.

C. The Quality Of Care Delivered Through MCO Plans Equals Or Exceeds The Quality Of Care Delivered Through Fee-For-Service Plans

As should be evident, there is no reason to expect that benefits-management techniques of the sort at issue here would adversely affect the quality of care received by plan beneficiaries, as compared to traditional indemnity plans. And, indeed, a large body of empirical evidence demonstrates that although managed-care organizations cover care at significantly lower cost than more traditional plans,[12] that care is of the same, or even higher, quality. In fact, health plans have been measuring and publicly reporting results on select quality measures for nearly a decade.

One recent study, for example, examined the occurrence of preventable hospitalizations in populations enrolled in managed-care and fee-for-service plans. By that measure, the quality of care delivered to enrollees of MCOs equaled or exceeded that of the care delivered to enrollees of fee-for-service plans with respect to four of the five medical conditions studied.[13] Other studies have concluded that, for example:

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[12] Dean G. Smith, *The Effects of Preferred Provider Organizations on Health Care Use and Costs*, Inquiry, Winter 1997/1998, at 278, 282 (U. Mich. School of Public Health study funded by the Robert Wood Johnson Foundation) (PPOs saved 12% per covered life per year when compared to a traditional indemnity plan with utilization review).

[13] L. Clark Paramore & Anne Clixhauser, *Assessments of Quality of Care for Managed Care and Fee-for-Service Patients Based on Analysis of Avoidable Hospitalizations*, 2 Value in Health 258 (1999).

- All indicators of timeliness and quality of care for Medicare heart attack patients were similar or higher for patients enrolled in HMOs compared to patients receiving FFS coverage. Patients enrolled in HMOs were significantly more likely than patients receiving FFS coverage to receive aspirin and beta-blocker therapy after heart attacks.[14]
- Angina patients enrolled in MCOs were likely to receive similar or better care, and were much more likely to be released from the hospital on guideline-recommended medications, than patients in FFS plans.[15]
- Patients enrolled in commercial HMOs who were hospitalized with congestive heart failure had the same or better quality of care as, and lower mortality rates than, those enrolled in commercial FFS plans.[16]
- Medicare HMO enrollees were more likely to have breast cancer diagnosed before the later stages of the disease, to receive breast-conserving surgery, and to obtain recommended radiation therapy than Medicare FFS enrollees.[17] Breast-cancer patients had at

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[14] Stephen B. Soumerai et al., *Timeliness and Quality of Care for Elderly Patients with Acute Myocardial Infarction Under HMO vs. Fee-for-Service Insurance*, 159 Archives Internal Med. 2013, 2017-2018 & fig. (1999).

[15] Nathan R. Every et al., *Influence of Insurance Type on the Use of Procedures, Medications, and Hospital Outcome in Patients with Unstable Angina: Results From the GUARANTEE Registry*, 32 J. of Am. Coll. of Cardiology 387 (1998).

[16] Edward F. Philbin et al., *Managed Care for Congestive Heart Failure: Influence of Payer Status on Process of Care, Resource Utilization, and Short-term Outcomes*, Am. Heart J., Sept. 1998, at 553.

[17] Gerald F. Riley et al., *Stage at Diagnosis and Treatment Patterns Among Older Women with Breast Cancer: An HMO and Fee-for-Service Comparison*, 281 JAMA 720 (1999).

least equal, and possibly better, survival outcomes.[18] And patients enrolled in HMOs were more likely to receive aggressive therapy for prostate cancer.[19]

- The likelihood of low-birth-rate deliveries in the California Medicaid program was lower in managed care arrangements than in the FFS payment group.[20]
- Managed care enrollees in the Wisconsin Medicaid program were more likely to receive superior prenatal care than patients enrolled in FFS plans.[21] California and Florida Medicaid maternal delivery outcomes were the same.[22]
- As a general measure of quality, 93% of patients enrolled in MCOs received recommended beta-blocker care after heart attacks, compared to 45% in the general population. Similarly, 81% of diabetes patients had their blood sugar measured regularly, compared to 24%; and 85% of pregnant women received recommended prenatal care, as opposed to 73%.[23]

The quality of care provided in a managed care setting compares equally well in the two contexts in which cost

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[18] Arnold L. Potosky et al., *Breast Cancer Survival and Treatment in Health Maintenance Organization and Fee-for-Service Settings*, 89 J. Nat'l Cancer Inst. 1683 (1999).

[19] Arnold L. Potosky et al., *Prostate Cancer Treatment and Ten-Year Survival Among Group/Staff HMO and Fee-for-Service Medicare Patients*, 34 Health Servs. Res. 525 (1999).

[20] Denise M. Oleske et al., *A Comparison of Capitated and Fee-for-Service Medicaid Reimbursement Methods on Pregnancy Outcomes*, 33 Health Servs. Res. 55 (1998).

[21] Arik Levinson & Frank Ullman, *Medicaid Managed Care and Infant Health*, 17 J. Health Econ. 351 (1998).

[22] Denise M. Oleske et al., *Effect of Medicaid Managed Care on Pregnancy Complications*, 95 Obstetrics & Gynecology 6 (2000).

[23] *Compare* National Comm. for Quality Assurance, *The State of Health Care Quality: 2002* 10 (2002) (using the "HEDIS"—Health Plan Employer Data and Information Set—measures for health plans) *with* McGlynn, *supra*, at 2642, 2643 tab. 5.

pressures are greatest, and out of which the present cases arise: prescription drug management and hospital utilization. As to drugs, a new study conducted by medical schools across the country considered patients with diabetes, congestive heart failure, and asthma, and concluded that (1) "managed care patients were more likely to use chronic disease medications than indemnity patients"; (2) "chronic disease patients in these managed care plans are more likely to receive both inexpensive and expensive medications"; (3) MCO health plans had a "markedly increased probability of using newer [drug] therapies" than indemnity plans; and (4) the differences among the two insurance groups could be explained by the fact that patients in indemnity plans "face higher out-of-pocket costs and managed care plans promote more aggressive medication use."[24] Noting that these findings may be "contrary to public perception," the authors point out that study results confirm previous research showing increased drug prescription patterns in health plans using disease-management techniques, which are not offered through traditional indemnity coverage.[25]

Similarly, as to hospitalization management, two new studies published in the New England Journal of Medicine find no adverse health impact resulting from reductions in hospital usage. By adopting a managed-care model, the Veterans Administration reduced acute-care hospital bed use by 55%. That marked decline in hospital use "did not curtail access to needed services and was not associated with serious consequences for chronically ill" beneficiaries.[26] Moreover, it did not result in a rise in non-hospital care. An earlier study, conducted by the Harvard Medical School, determined that early hospital discharge programs for mothers

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[24] Randall S. Stafford, *Chronic Disease Medication Use in Managed Care and Indemnity Insurance Plans*, 38 Health Servs. Res. 595, 595 (2003).

[25] *Id.* at 606.

[26] Carol M. Ashton et al., *Hospital Use and Survival among Veterans Affairs Beneficiaries*, 349 New Eng. J. Med. 1637, 1637 (2003).

and newborns had no effect on the health outcomes of the newborns. Shorter stays were, moreover, correlated with newborn examinations on the third or fourth day after discharge, a procedure that results in better health outcomes, and is therefore recommended by treatment guidelines.[27]

This evidence that managed-care techniques preserve or even enhance quality, while significantly restraining costs, soundly refutes any suggestion that ERISA has failed plan beneficiaries by precluding them from challenging plan administrators' *coverage* decisions under state law. It also helps explain why federal law has long actively encouraged the development and use of managed-care techniques;[28] and why public-sector health-care systems, ranging from the Veterans Administration[29] to the Federal Employees Health Benefits Program[30] and the Department of Defense's TRICARE program[31] (the latter two of which are run by private

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[27] Jeanne M. Madden et al., *Effects Of A Law Against Early Postpartum Discharge On Newborn Follow-Up, Adverse Events, And HMO Expenditures*, 347 New Eng. J. Med. 2031 (2002).

[28] *See* Federal Health Maintenance Organization Act of 1973, 42 U.S.C. § 300e-9 (requiring employers with at least 25 employees to offer a federally qualified HMO as an option to their employees); Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §§ 4204(a) (1990) (repealing prohibition on physician-incentive plans in Medicare and Medicaid HMOs); Social Security Act, 42 U.S.C. § 1395mm(i)(8) (Medicare managed care); *id.* § 1396b(m) (Medicaid managed care); *id.* § 1395w-21 (Medicare+Choice).

[29] The Veterans Health Administration runs the largest health care system in the United States. *See* Ashton et al., *supra*, at 1638; VHA General Information, *at* http://www1.va.gov/Health_Benefits/page.cfm?pg=1.

[30] The Federal Employees Health Benefits Program covers 8.3 million federal employees and retirees and their families. *See* Derek Hunter, *Health Care Choice and Patient Satisfaction* (2003), *available at* http://www.heritage.org/Research/HealthCare/wm259.cfm.

[31] TRICARE, the Department of Defense's health care program for non-active-duty military beneficiaries—retired personnel and family members of personnel—covers some 8.7 million people with a budget of $22 billion; the program processes 1.8 million claims weekly. *See* Dep't of Defense, TRICARE *Stakeholders' Report* (2003), *available at* http://www.tricare.osd.mil/stakeholders/downloads/stakeholders_2003.pdf.

administrators under contract with the government), have embraced such techniques in their own operations. Benefit-management programs are not about increasing profits, or reducing care. They are about the prudent management of scarce *joint* resources, to ensure the ability to provide the *right* care to each member with a covered need.

III. Allowing State Tort Suits Challenging Plan Coverage Decisions Would Unnecessarily Increase Costs And Reduce Coverage

Although it has succeeded in providing high-quality coverage for millions of Americans, the employment-based coverage system is under severe strain. Despite the advances in cost-containment made possible by managed-care techniques, national spending on health care surpassed 14% of GDP by 2001.[32] The next year, spending per privately-insured person rose 9.6% —well over three times the rate of increase in the Nation's gross domestic product.[33]

The greatest increases in health costs arise from precisely the sources highlighted by these cases: prescription drugs and hospitalization. The cost of prescription drugs tripled in the decade after 1990, reaching $140 billion in 2001.[34] It rose almost 16% in that final year alone and over 13% last year.[35] These figures reflect an increase in usage (the number of prescriptions increased 74% from 1992 to 2002, while the U.S. population grew only 12%); increases in retail prescription prices; and a shift toward newer, higher-

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[32] *See* Katharine Levit et al., *Trends in U.S. Health Care Spending, 2001*, Health Affairs, Jan./Feb. 2003, at 154, 154, 156 Ex. 2.

[33] Bradley C. Strunk & Paul B. Ginsburg, *Tracking Health Care Costs: Trends Stabilize but Remain High in 2002*, Health Affairs, June 11, 2003, at 266, 268 & Ex.1.

[34] *See* Levit et al., *supra*, at 158 Ex.5.

[35] *Id.* at 156 Ex.2; Strunk & Ginsburg, *supra*, at 268 Ex. 1.

priced name-brand drugs.[36] In light of changing age demographics and usage trends, "U.S. spending for prescription drugs is expected to continue to rise rapidly, reaching $445.9 billion (17% of personal health care spending) by 2012."[37] Overuse of antibiotics alone results in as much as $5 billion in unnecessary expenditures each year.[38]

Growth in hospitalization costs moderated in the 1990s—due in large part to strict utilization review.[39] By 2000, however, hospitalization again surpassed medication as the key cost driver,[40] and hospital costs "continue[] to drive overall health care spending trends."[41] Moreover, as with drug costs, overuse of inpatient care for medical treatments that can be performed safely in an outpatient setting unnecessarily raises both the financial and the human costs of care. According to one study, for example, preventable hospital-acquired infections claim at least 20,000, and perhaps more than 60,000, lives each year, and result in up to $18 billion in unnecessary expenditures.[42]

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[36] The Kaiser Family Foundation, *Prescription Drug Trends* 2 (May 2003) (citing www.imshealth.com), *available at* http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14267.

[37] *Id.* (citing *Health Spending Projections for 2002-2012*, Health Affairs (Feb. 7, 2003)).

[38] Midwest Business Group on Health, *Reducing the Costs of Poor-Quality Health Care Through Responsible Purchasing Leadership* iii (2003) ("MBGH Report").

[39] Bradley C. Strunk et al., *Tracking Health Care Costs: Hospital Care Surpasses Drugs as the Key Cost Driver*, Health Affairs, Sept. 26, 2001, at 39, 44-45.

[40] Strunk et al., *supra*, at 39.

[41] Strunk & Ginsburg, *supra*, at 266.

[42] *See* MBGH Report at iii. At the other extreme, underdiagnosis and inadequate treatment of diabetes results in direct and indirect costs of $132 billion annually, as well as tens of thousands of cases of premature death, amputations, kidney disease, and blindness. Underdiagnosis and the failure to use pharmacy and outpatient services to treat depression results in costs of $80 billion per year, while poor management of asthma costs $18 billion. Underuse of influenza and pneumococcal vaccinations

Whichever driver leads at any given moment, radically increasing costs in these two sectors pose a serious challenge to the continued vitality of employment-based health coverage.[43] Between spring 2002 and spring 2003, monthly premiums for employer-sponsored health insurance rose 13.9%—over six times the rate of inflation, and the third consecutive year of double digit premium increases.[44] At the same time, employees are paying an increasing percentage of plan costs, as well as larger deductibles and co-payments.[45] In turn,

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results in the death of between 10,000 and 20,000 individuals each year, while inadequate care after a heart attack results in 18,000 unnecessary deaths. In all, this survey concludes that $420 billion is spent each year as a direct result of care diverging from objective quality standards (not including indirect costs, such as reduced productivity from absenteeism, which the study estimates costs an additional $105 to $210 billion). Private purchasers absorb about one-third of these costs, which is estimated to cost the typical employer between $1,900 and $2,250 per covered employee per year. As discussed above, one of the salient promises of managed-care techniques is the potential to reduce the costs of *both* over- *and under*-utilization of care.

[43] *See* Kaiser Foundation 2003 Survey at 2 ("When employers were asked which factors contributed 'a lot' to increases in health insurance premiums, firms were most likely to point to higher spending for prescription drugs (61%) and hospital services (55%).").

[44] *See id.* at 1.

[45] *See* Mercer Human Resource Consulting, *Surprise Slow-Down In US Health Benefit Cost Increase: Employers Shift Costs To Employees, Take Steps To Improve Workforce Health* (Dec. 8, 2003) (summarizing Mercer's *National Survey of Employer-Sponsored Health Plans 2003*), *available at* http://www.mercerhr.com/pressrelease/details.jhtml/dynamic/idContent/1121535;jsessionid=NEIHSHTI0U0EGAAJAADQOCAKMZSI4I2C; Milt Freudeinheim, *Employees Paying Ever-Bigger Share for Health Care*, N.Y. Times, Sept. 10, 2003, at Al (reporting on Kaiser Foundation 2003 Study showing that almost 2/3 of large employers that sponsored health plans raised the amounts that employees are contributing to the cost of their health plans this year, and 79% say they will do so again in 2004); The Business Council of New York State, Inc., *Compensation Data New York 2003* (2003) (survey of New York employers reflects that, in a 12-month period ending in April 2003, more than 1/3 of employers increased the employee portion of health insurance premiums, and nearly 1/3 increased deductible levels). The Kaiser Foundation reports that recently there has been "a greater level of interest"

rising health insurance premiums have been "clearly linked" to rising rates of the uninsured.[46]

Particularly in light of these existing pressures on voluntary employer health plans, the Fifth Circuit was wrong to adopt an interpretation of federal law that would permit state tort suits based on plan coverage decisions. To begin with, of course, that interpretation is untenable in light of ERISA itself and this Court's cases, as the petitioners' briefs amply demonstrate. Even if the statute and precedents were less clear, however, allowing such suits would be deeply misguided.

1. *First*, there is no need to permit state tort suits in order to protect ERISA beneficiaries. Despite what one might infer from the stories included by plaintiffs' lawyers in their complaints (and perforce accepted by judges *as though* true for purposes of ruling on motions to dismiss), there is no reason to think that there is a widespread problem of plan participants wrongly denied coverage for necessary care, and then subjected to bad medical outcomes that would have been prevented had the desired drug or service been provided. To the contrary, as discussed above, the incentives of sponsors, employees, and plan administrators in this regard are aligned, not antagonistic. MCOs deny only a small percentage of coverage claims, and only a few of those denials are based on a failure to meet pre-authorization criteria.[47]

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among very large employers in insurance featuring very high deductibles (over $1000). *See* Kaiser Foundation 2003 Study at 2-3. Because such employers "historically have been innovators in the market, [this] may portend future growth of this option." *Id.*

[46] Strunk & Ginsburg, *supra*, at 266.

[47] Of the less than 2% of plan enrollees who are initially denied coverage, *see* Carole Roan Gresenz et al., *A Flood of Litigation? Predicting the Consequences of Changing Legal Remedies Available to ERISA Beneficiaries* (1999), *available at* http://www.rand.org/publications/IP/IP184/, only *6%* of denials resulted from failure to meet pre-authorization criteria, compared to denials because of: filing of duplicate claims (18%); prior payment of a capitated rate (10%); failure to adhere to plan procedures (including failure to request pre-authorization) (18%);

Moreover, as discussed above, health outcomes under managed-care arrangements typically equal or surpass those under traditional fee-for-service plans.[48] Plan coverage guidelines are designed to provide, not withhold, payment for care—*if* the objective medical evidence suggests that that care is likely to produce a better outcome than some other alternative.

Moreover, all plans have mechanisms available for the fast internal review, and often for independent outside review, of coverage denials. ERISA itself requires procedural protections such as effective notice of coverage denials and a reasonable opportunity for review of such decisions,[49] and the Secretary of Labor has issued comprehensive regulations governing the appeal process that include requiring, when appropriate, review in consultation with a medical professional,[50] and initial and final decisions that provide specific reasons for denial, and references to pertinent plan provi-

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submission of incomplete or inaccurate information (14%); or the fact that the patient is not a plan member (7%). *See* AAHP, *Portrait of a Changing HMO Industry* 3 & fig. 2 (2001).

[48] *See supra*, pp. 14-19.

[49] *See* 29 U.S.C. § 1133(1) ("In accordance with regulations of the Secretary, every employee benefit plan shall . . . provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant . . . ."); *id.* § 1133(2) (plans must "afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim").

[50] *See* 29 C.F.R. § 2560.503-1(h)(1) (benefit plan must establish and maintain a procedure "under which there will be a full and fair review of the claim"); *id.*§ 2560.503-1(h)(2)(iv) (plan must "[p]rovide for a review that takes into account all comments, documents, records, and other information submitted by the claimant relating to the claim"); *id.* § 2560.503-1(h)(3)(iii), (4) ("[I]n deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment," the administrator "shall consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment.").

sions.[51] Every state also requires MCOs to establish consumer grievance and appeals processes for their insured plans,[52] and 42 states and the District of Columbia accord beneficiaries the right to appeal denials of insurance coverage to an independent medical review entity.[53]

The resulting appeals structure offers plan beneficiaries effective review. Indeed, initial coverage denials are reversed about half the time, even when appeals arise *after* a beneficiary has undergone treatment, without first securing plan authorization.[54]

Finally, there is the familiar remedy that Congress chose to provide in ERISA: A suit "to recover benefits due to [a beneficiary] under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." 29 U.S.C. § 1132(a)(1)(B). Importantly, that remedy is as practical and effective today as it was 30 years ago to a plan beneficiary who had a dispute with a plan or insurer about the coverage of a given treatment, drug, or service under the terms of a wholly traditional, indemnity-style health insurance plan.

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[51] *See* 29 C.F.R. § 2560.503-1(g) (initial decision); *id.* § 2560.503-1(j)(1), (2) (final decision).

[52] *See* Lillian MacEachern, Health Policy Tracking Service, *Issue Brief: Consumer Grievance Procedures: Internal & Independent Appeals (Year-End Report - 2002)* (2002).

[53] *See* National Conference of State Legislatures, *Managed Care Insurer Liability* (2003), *available at* http://www.ncsl.org/programs/health/liable.htm (updated Nov. 3, 2003); *see also Rush Prudential HMO* v. *Moran*, 536 U.S. 355 (2002) (Illinois statute requiring HMOs to provide independent review was not preempted by ERISA, where HMO was properly treated as an insurer).

[54] *See* AAHP, *Independent Medical Review of Health Plan Coverage decisions: Empowering Consumers With Solutions* 1 (2001) (concluding that 49% of cases decided by independent review are reversed); *see also* Gresenz et al., *A Flood of Litigation?*, *supra*, at 189 (enrollees won 36% of prospective appeals and 89% of retrospective appeals in one large HMO studied, and 70% of prospective and 78% of retrospective appeals in the other).

There is, accordingly, no reason to think that simply because coverage determinations are now often made earlier and in a more organized manner, the remedy that Congress originally provided for coverage disputes has somehow become inadequate or in need of supplementation.

2. *Second*, allowing state suits regarding coverage decisions would be affirmatively harmful. The prospect of such litigation would significantly complicate plan design, funding, and administration. Contract-based costs of expected care, relatively predictable over groups of beneficiaries, will be subject to unpredictable, but quite possibly significant, potential tort liabilities. That sort of uncertainty will make it difficult for sponsors and administrators to budget, including setting appropriate employee premiums, deductibles, or co-payment amounts. Moreover, differing state standards will hinder the implementation of nationwide, evidence-based coverage guidelines and care initiatives (such as disease-management plans), and the uniform administration of both benefits and review mechanisms for initial coverage decisions. At a minimum, these new complications would materially increase the cost of providing coverage through a voluntary plan, and thus undermine a core purpose of ERISA's uniform regulatory scheme. As one commentator has put the point:

> Removal of ERISA preemption and adoption of more state liability laws could lead to an environment where HMOs and managed care plans are defending a number of lawsuits against a number of different plaintiffs in a number of different states arising under a number of different types of causes of action. This is exactly the environment from which Congress was trying to protect employee benefit plans generally when it enacted ERISA in 1974.[55]

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[55] Matthew J. Binette, Comment, *Patients' Bill of Rights: Legislative Cure-All or Prescription for Disaster?*, 81 N.C. L. Rev. 653, 693-94 (2003).

The response of plan sponsors and administrators is not hard to predict. Some will restrict benefits, and/or increase required employee contributions, to counter-balance the higher costs of running their plans. Others will seek to avoid litigation over individual coverage determinations by removing any discretionary element from their coverage categories—thus contracting, not expanding, the availability of benefits in cases where the cost-effectiveness of treatment is debatable. Still others may discontinue, or decline to adopt, health care coverage entirely, rather than face the uncertainty, litigation exposure, and certainly higher costs that would accompany the new regime.[56] In any event, the decision below will significantly undermine Congress' goal of encouraging employment-based health coverage, without promising any commensurate increase in protection for those individuals who do remain covered by ERISA plans.

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[56] While nearly all large employers (those with 200 or more workers) presently offer health benefits, the figure for smaller companies is only 65%. Kaiser Foundation 2003 Survey at 38.

CONCLUSION

The decisions of the court of appeals should be reversed.

Respectfully submitted,

STEPHANIE W. KANWIT
CHRISTINA S. YEHLE
AAHP-HIAA
1129 20th Street, N.W.
Washington, D.C. 20036
(202) 778-3202

SETH P. WAXMAN
Counsel of Record
EDWARD C. DUMONT
KENNETH A. BAMBERGER
WILMER, CUTLER & PICKERING
2445 M Street, N.W.
Washington, D.C. 20037
(202) 663-6000

Counsel for Amicus Curiae AAHP-HIAA

ALAN JAY LIPSITZ
BLUECROSS BLUESHIELD ASSOCIATION
1310 G Street, N.W.
Washington, D.C. 20005
(202) 942-1278

Counsel for BlueCross BlueShield Association

SUSAN RELLAND
LYNN DUDLEY
AMERICAN BENEFITS COUNCIL
1212 New York Ave., N.W.
Washington, D.C. 20005
(202) 289-6700

Counsel for American Benefits Council

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